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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,567	01/23/2004	Rudolf Gilmanshin	C0989.70045US01	4885
7590 02/08/2008				
Maria A. Trevisan				
Wolf, Greenfield & Sacks, P.C.				
600 Atlantic Avenue				
Boston, MA 02210				
			EXAMINER	
			SKOWRONEK, KARLHEINZ R	
			ART UNIT	PAPER NUMBER
			1631	
			MAIL DATE	DELIVERY MODE
			02/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/763,567	Applicant(s) GILMANSHIN ET AL.	
	Examiner Karlheinz R. Skowronek	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6 and 8-55 is/are pending in the application.
- 4a) Of the above claim(s) 13, 19-20, 22, 37, 47-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-12, 14-18, 21, 23-36, 38-46 and 50-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/19/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

Claims 1-4, 6, and 8-55 are pending.

Claims 5 and 7 are cancelled.

Claims 13, 19-20, 22, 37, 47-49 stand withdrawn as being directed to a non-elected invention.

Claims 1-4, 6, 8-12, 14-18, 21, 23-36, 38-46, 50-55 are being examined.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 19 November 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 6, 8-12, 14-18, 21, 23-36, 38-46, 50-55 are drawn to a process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999))). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1-4, 6, 8-12, 14-18, 21, 23-36, 38-46, 50-55 do not require production of a tangible result in a form that is useful to the user of the process. The process comprises obtaining intensity profiles, aligning individual intensity profiles, combining the aligned profiles to generate a population profile, selecting a peak in the population profile, combining individual profiles to generate a peak profile, and comparing the peak profile with the sample profile. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, or to a user, or in a graphical format, or in a user readable format, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 55 are unclear with respect to the "the intensity profile" recited at line 11 in claim 1 and at line 10 in claim 55. The lack of clarity arises because the intensity profile does not indicate which one of a plurality of intensity profiles that are obtained in the first step is stored.

Claim Rejections - 35 USC § 102

Applicant's arguments, see remarks p. 9, filed 19 November 2007, with respect to the rejection of claims 1-4, 6, 9-11, 18, 21, 23, 28, 39, and 53 as anticipated by Taylor et al have been fully considered and are persuasive. The rejection of claims 1-4, 6, 9-11, 18, 21, 23, 28, 39, and 53 has been withdrawn in view of the amendment to claim 1.

Applicant's arguments, see remarks p. 9-10, filed 19 November 2007, with respect to the rejection of claims 1-4, 6-12, 14, 16-18, 21, 23-24, 26, 44-46 and 50-52 as anticipated by Chan have been fully considered and are persuasive. The rejection of claims 1-4, 6-12, 14, 16-18, 21, 23-24, 26, 44-46 and 50-52 has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6, 8-12, 14, 16-18, 21, 23-24, 26, 28, 39 44-46, and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al (PG PUB 2003/0082538), and in view of Chan (WO 98/35012).

The claims are directed to a method for analyzing polymer intensity data from a sample comprising obtaining intensity profiles from individual labeled polymers contained in the sample, aligning individual intensity profiles from individual labeled polymers with respect to an alignment reference point, combining aligned individual intensity profiles to generate a population profile, selecting a peak in the population

profile and obtaining individual intensity profiles that contribute to peak, combining individual intensity profiles that contribute to the peak to generate a peak profile, and comparing the peak profile with the population profile storing the intensity profile as a intensity vs. length profile. Further embodiments are drawn to the type of polymer, fluorescence data, labeling techniques, and data manipulations.

Taylor et al teach a method of analyzing polymer populations in which intensity profiles from individual labeled polymers are obtained ([0156]). The profiles are aligned with respect to an alignment reference point and combined to generate a sample population profile (fig. 16). Taylor shows selecting a peak in the sample profile and obtaining intensity profiles that contribute to the peak then combining the individual intensity profiles to generate a peak profile and comparing the peak profile with the sample profiles (fig 18 vs. fig16). Taylor show the peak profile consists of a subset of peaks from the sample profile (compare figure 16 to figure 18) Taylor shows storing intensity profiles as intensity vs. length profiles [0134 and 0156]. Taylor teaches that the sample can contain a heterogeneous mixture of polymers that are of different sizes/lengths [0134] and the mixtures of polymers have different sequences [0136]. Taylor teaches the sample is separated according to size prior the alignment [0134]. Taylor teaches that the intensity is fluorescence and profiles are fluorescence profiles [0156]. Taylor et al teaches the polymers are embedded in a gel matrix [0232]. Taylor teaches a computer-implemented method (abstract, line 1-2). Taylor teaches the polymer is the nucleic acid, DNA [0030]. Taylor teaches the intensity profiles are obtained from individual polymers in flow [0127]. Taylor et al show in figure 16, a

sample profile that is an average of multiple profiles and in figure 17, a peak profile that is an average of multiple peak profiles.

Taylor does not show polymers labeled with sequence specific probes.

Chan teaches a method for analyzing polymer intensity data from a sample. To accomplish the analysis, Chan obtaining fluorescence intensity data from a collection of labeled nucleotide polymers (p. 18, line 25-28, p. 11, line 32-34). The polymers can be labeled at specific sites or labeled randomly (p. 18, line 31-32). The random labeling reads on the further embodiments of sequence nonspecific labels. Chan describes the use of reference points to align profiles from individual polymers (p. 63, lines 25-31). Chan teaches intensity data from labeled polymers (p. 23, line 17-22). Chan teaches intensity profiles stored as intensity vs. length profiles (p. 68, lines 7-15). In another embodiment, Chan teaches a method where the sample contains a heterogeneous mixture of polymers, differently sized fragments and with different sequences (p. 162, lines 8-9 and p. 74, lines 23-24). In another embodiment, Chan teaches a method where profiles are intensity versus length profiles and intensity is from fluorescence (p. 9, lines 9-13 and 33-35). In another embodiment, Chan teaches a method where the polymers are labeled with a sequence specific probe (p. 68, line 18 to p.69 line 1). In another embodiment, Chan teaches a method where the method is implemented on a computer (p. 58, lines 29-32). In another embodiment, Chan teaches a method where the polymer is a nucleic acid that is DNA, and further genomic DNA (p. 8, lines 28-29). In another embodiment, Chan teaches a method where the reference point is an internal reference point and the reference point is a sequence specific probe (p.15, line

15-16). In another embodiment, Chan teaches a method where the polymers are in flow (col. 27, line 5-9). In another embodiment, Chan teaches a method where the population profile is an average population profile (p. 63, lines 18-24). In another embodiment, Chan teaches a method where polymers in the sample are sorted according to size prior to aligning individual intensity profiles (p. 119, line 35). In another embodiment, Chan teaches a method where the peak profile is an average peak profile (p. 40, line 31). In another embodiment, Chan teaches a method where peak is selected based on intensity (p. 40, lines 24-26). In another embodiment, Chan teaches a method where the polymer is completely stretched, partially stretched, or uniformly stretched (p. 101, lines 17-19). In another embodiment, Chan teaches a method where the peak is visible in an intensity vs. length profile (figs. 2 and 9). In another embodiment, Chan teaches a method where the peak corresponds to bin counts (p. 44, lines 6-7 and lines 11-12).

It would have been obvious to one of skill in the art to modify the method of polymer analysis of Taylor et al with the sequence specific probes of Chan because Chan shows by doing so the polymers labeled with sequence specific probes have a characteristic signature that allow the polymers to be identified from mixtures of similar polymer of different sequence, an advantage when testing mixtures of polymers. One of skill in the art would have been capable of applying sequence specific probes to a method of polymer analysis and the results would have been predictable to one of skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4 February 2008

/KRS/
Karlheinz R. Skowronek
Assistant Examiner, Art Unit 1631

/John S. Brusca/
Primary Examiner
Art Unit 1631